

**THE EFFICACY OF THE BITESTRIP^R
IN DETERMINING PATIENTS
AWARENESS OF NOCTURNAL BRUXISM
By**

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ABSTRACT

The Efficacy of the BiteStrip in Determining Patients Awareness of Nocturnal Bruxism

By

Emily R. Tolley, DDS

The presence of nocturnal bruxism in patients undergoing prosthodontic treatment can have a significant effect on the long term success of restorations. Patients who experience nocturnal bruxism are at risk for dysfunction of the stomatognathic system. This includes TMJ, muscles of the head and neck, the teeth and any restorations, and the periodontium. This condition affects the diagnostic treatment planning, treatment goals, and treatment prognosis of any prosthodontic treatment.

The purpose of this study is to compare the incidence of nocturnal bruxism determined by an electronic device when compared to self-reporting from verbal and written dental histories.

The hypothesis of this is that prevalence of nocturnal bruxism is actually higher than self-reported by patients from verbal and written dental histories.

The materials and methods of this study consisted of 20 patients from West Virginia University Graduate Prosthodontic program. Each patient was given a questionnaire to complete. If the patient showed at least one symptom of bruxism then they were given both written and verbal directions on how to use the BiteStrip. The patient would use it as directed and return it within one week of use.

The results showed that 11 out of the 20 patients that stated that they did not brux, 6 actually did brux. 70% of our patient population exhibited nocturnal bruxism. Wilcoxon/Kruskal Wallis test of ranked sums was analyzed for all seven of the questions from the questionnaire, but only question #1 and #2 were statistically significant.

In conclusion the BiteStrip demonstrated 70% of the patients registered as bruxers. A fairly high percentage of those who scored as bruxers with the BiteStrip^R were unaware that they did brux. This device proved to be effective in determining patient's awareness of nocturnal bruxism. Since many patients are unaware of their bruxism this devise should be very helpful to clinicians in determining which patients need treatment for bruxism.

I would like to dedicate this research to my parents. Both of you mean the world to me and without your love I would never have been here. Thank you for giving me every opportunity a daughter could ask for and the constant support and guidance that you have provided. I will never be able to repay you for all you have done. Every accomplishment has been because of you both. Thank you.

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To Granny...this is it....it is now "one of these days". I did it, and I love you dearly.

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CHAPTER 1

INTRODUCTION

Background

Prior to any manipulation of the masticatory apparatus, whether a single tooth restoration or extensive reconstruction of occlusion, one must determine the desired treatment position of the condylar head in the glenoid fossa. This should be based on the functional anatomy of the temporomandibular joint since the treatment position of the condyle, if possible, should not violate any of the anatomical, biological, or physiological principals affecting the integrity of the tissues associated with the mandibular function.

The mandibular arch is related to the maxillary arch by the temporomandibular joint, the ligaments that compliment the joint or attach the mandible to the cranium, the muscles of mastication, and other supportive structures. Although the temporomandibular joint is constantly being remodeled under the influence of the erupting primary teeth and permanent dentition, as well as periodic loss of teeth, it still remains the only point of reference of the mandible to the maxilla.¹ It is this understanding which guides our treatment of temporomandibular disorders (TMD). One of the common complaints and signs of patients suffering from TMD is grinding of the teeth or bruxism.¹

Although no specific data exists regarding the social impact of temporomandibular disorders, TMD is estimated to account for as much as thirty billion dollars a year in lost productivity. Americans lose 550 million work days every year due to symptoms associated with TMD, with facial pain and headache being the most common complaints.¹ Accordingly, analgesics directed at these symptoms are among the top selling over the counter medicines in our society

Sleep disorders are very common: over forty million American adults suffer from chronic rest-related problems. An additional twenty million to thirty million get inadequate sleep. Anxiety, exhaustion and concentration difficulties are all common symptoms of excessive daytime fatigue. These problems may be caused by a variety of physical, medical, psychiatric or external factors. The International Classification of Sleep Disorders (ICSD) lists over 84 different types in four different categories: dyssomnias, parasomnia, medical/psychiatric problems, and proposed disorders.¹

With all the different types of sleep disorders and with all the factors incorporated within each category it is difficult to accurately diagnose patients with nocturnal bruxism. Diagnosis is much too often mistaken as a non-vital piece of information in the dental office. The signs and symptoms of bruxism are wear facets, decreased vertical dimension, hypertrophy of the facial muscles, facial muscle soreness and/or pain and the signs/symptoms are not conspicuous in most instances.² However, certain signs and symptoms are indicative, although not pathognomonic or diagnostic. By careful observation of these signs and symptoms, severe cases of bruxism can usually be discovered. Since most of the patients with bruxism are unaware of the habit, a case history is may be unreliable. By informing a patient about the possibility of bruxism and

having them inquire of family and friends, a positive history can often be obtained. In many instances, the habit of bruxism is brought from the subconscious to the conscious level by pointing out to the patient the possibility of the presence of such a habit.

Bruxism is of extreme clinical importance since the presence or absence of bruxism indicates a patient's individual reaction to his occlusal imperfections. It has been hypothesized that the presence of bruxism documents the low tolerance level to occlusal interference. On the other hand, a person with considerable occlusal interference and no bruxism does not tend to develop traumatic occlusion or other functional disturbances even if restorative or prosthetic procedures should end up slightly short of perfection.

The purpose of this study is to compare the incidence of nocturnal bruxism determined by an electronic device when compared to self-reporting from verbal or written dental histories.

Statement of the Problem

Nocturnal bruxism is a condition that is often undiagnosed and overlooked by dentists. Currently there is no accurate, convenient, and cost efficient method to identify patients who experience nocturnal bruxism.

Significance of the Study

The presence of nocturnal bruxism in patients undergoing prosthodontic treatment can have a significant effect on the long term success of restorations. Patients who experience nocturnal bruxism are at risk for dysfunction of the stomatognathic system. This includes TMD, severe wear, tooth mobility, pain in the muscles of the head and neck, the teeth, and the periodontium. This condition affects the diagnostic treatment planning, treatment goals, and treatment prognosis of any prosthodontic treatment. Bruxism is considered a possible contraindication for dental implants due to the inability of implants to tolerate lateral forces.² Bruxism is also considered to be a contraindication for ceramic restorations due to a concern for fracturing of porcelain. It is therefore very important for the restorative dentist to determine whether his/her patients bruxes.

Hypothesis

The prevalence of nocturnal bruxism is actually higher than self-reported by patients from written and verbal dental histories.

Definition of Terms

Bruxism: the parafunctional grinding of teeth

Nocturnal Bruxism: an oral habit consisting of involuntary rhythmic nonfunctional grinding, gnashing or clenching of teeth in other than chewing movements of the mandible

Dyssomnias: conditions which causes a disruption of the body's natural resting and waking patterns. Dyssomnias may be extrinsic or intrinsic and may be caused by problems with a person's circadian rhythm or internal clock.

Parasomnia: conditions which interrupt sleep. They are caused by difficulties with arousal or sleep transitions. Some forms of parasomnia also hinder the transition from one sleep stage to another.

TMJ: the articulation of the condylar process of the mandible and the interarticular disk with the mandibular fossa of the squamous portion of the temporal bone; a diarthrodial, sliding hinge joint;

TMD: abnormal, incomplete, or impaired function of the temporomandibular joint(s)

Parafunctional Activity: disordered or perverted function

EMG: the graphic recording of the electrical potential of muscle

Nocturnal EMG: electromyographic registration made during sleep

BiteStrip^R: a single use disposable device as a front line screener for nocturnal bruxism.

It is a miniature electronic system comprising of:

- Two pre-gelled skin EMG electrodes and an EMG amplifier, for acquiring nocturnal EMG signals from the masticatory muscles.
- A CPU for running real-time software that analyzes EMG strength patterns and for detecting and counting each bruxing episode.
- A permanent chemical display for presenting the study outcome in the morning.
- A lithium battery
- All the elements are integrated onto a single flexible substrate

Splint Therapy: in dentistry, the joining of two or more teeth into a rigid unit by means of fixed or removable restorations or devices to inhibit or prevent movement

Maximal Intercuspal Position: the complete intercuspation of the opposing teeth independent of condylar position, sometimes referred to as the best fit of the teeth regardless of the condylar position

Assumptions

Patients with little or no bruxing will likely not be interested in seeking treatment for bruxism.

Limitations

Bruxing differs in each patient by frequency, duration, and time.

The age of the patient.

The gender of the patient.

Health history of patients.

Accuracy of BiteStrip

Patients must return for a second evaluation.

Diagnosis may not be exact.

Delimitations

Patients must be 18 years or older; if not 18 then must have written consent by adult.

Patients show some signs or symptoms of bruxism.

Consist of 20 fully dentate individuals with no past or present history of TMD or pathology.

Subjects must have orthopedic stable relationship in maximum intercuspation

Individuals did not undergo any invasive or irreversible procedures in this study.

Patients do not get the required 4 hours of sleep or they receive more than 12 hours.

CHAPTER 2

LITERATURE REVIEW

I. What is Bruxism?

What is bruxism? The word bruxism is taken from the Greek word brychein: gnashing of teeth. In the Academy of Prosthodontics glossary bruxism is defined as the parafunctional grinding of teeth. Bruxism unfortunately means different things to different experts. It can best be described as the involuntary, unconscious, and excessive grinding, tapping or clenching of the teeth. When it occurs at night it is called sleep bruxism, or nocturnal. A few people brux while they are awake, in which case the condition is referred to as wakeful bruxism, or diurnal.⁵

Perhaps the most significant dental sign of bruxism is occlusal or incisal attrition patterns that do not conform to or coincide with normal masticatory or swallowing wear patterns. The mechanism of excessive wear associated with bruxism is, according to Uhlig², based on the loosening and crushing of enamel prisms between contacting enamel surfaces, which provides the grit necessary for rapid wear of the enamel. The wear pattern of longstanding bruxism is often very uneven and usually more severe on anterior than on posterior teeth in the natural dentition.²

Forces of tooth contacts and Bruxism

In evaluating the effect of tooth contacts on the structures of the masticatory system, two factors must be considered: the magnitude and the duration of the contacts.

A reasonable way to compare the effects of functional and parafunctional contacts is to be evaluate the amount of force placed on the teeth in pounds per second per day for each activity.

It has been estimated that during each chewing stroke an average of 58.7 pounds of force is applied to the teeth for 115 msec.³ This yields 6.75 lb-sec per chew.⁴ In view of the fact that an estimated 1800 chews occur during an average day, we can see that the total occlusal force-time activity would be 12,150 lb-sec per day.⁵ The forces of swallowing must also be considered. Persons swallow some 146 times⁶ a day while eating. Because it is estimated that 66.5 pounds of force is applied to the teeth for 522 msec during each swallow, this comes to 5068 lb-sec per day. Thus the total force-time activity for chewing and swallowing is about 17,200 lb-sec per day.

Tooth contacts during parafunctional activity are more difficult to evaluate since little is known regarding the amount of forces applied to the teeth. It has been demonstrated that a significant amount of force over a given period can be recorded during nocturnal bruxism.^{7,8,9} Rugh and Solberg⁷ established that a significant amount of muscle activity consists of contractions that are greater than those used merely in swallowing and are sustained for a second or more. Each second is considered a unit of activity. Normal nocturnal muscle activities average about 20 units/hour. If a conservative estimate of 80 lb of force per second is used for each unit, then the normal nocturnal activity for eight hours is 12,800 lb-sec/night. This is considered normal activity and not of the bruxing patient. A patient who exhibits bruxing behavior can easily produce 60 units of activity per hour. If 80 lb of force is applied per second, this is three times the amount of normal functional activity per day. 80 pounds of force

represents only half the average maximum force that can be applied to teeth.³ If 120 lb of force is applied, the force time activity is 57,600 lb-sec/day. It can easily be appreciated that the force and duration of tooth contacts during parafunctional activity pose a much more serious consequence to the structures of the masticatory system than those of functional activity.

What are the major causing factors of bruxism?

The cause of bruxism is not completely clear. Although considerable light has been shed on the problem, there are enough unexplained observations to indicate there is still much to learn. One thing seems certain: there is no single factor that is responsible for all bruxing. It is also rather evident that there is no one single treatment that is effective for eliminating or even reducing all bruxing.

These factors have been shown to increase the risk of nocturnal bruxism:

- Psychological stress/anxiety
- Obstructive Sleep Apnea syndrome
- Smoking
- Caffeine
- Alcohol
- Drug Abuse (e.g., cocaine, amphetamine, Ecstasy)
- Temporomandibular disorders (TMD)

- Age: Bruxism is common in young children, but usually disappears by age 10. In adults, the condition is common between the late teen years and the 40s. It tends to decrease with older age.
- Familial/Genetic factors
- Occlusal factors
- Sleep factors

A. Malocclusion

Over the years, a great deal of controversy has surrounded the etiology of bruxism and clenching. Early on, the profession was quite convinced that bruxism was directly related to occlusal interferences.^{10,11,12} Treatments therefore, were directed toward correction of the occlusal condition. More recent studies¹³ do not support the concept that occlusal contacts cause bruxing events.

In some cases, bruxism may commence shortly after such dental procedures as fillings, crowns, or bridges; after an injury to the mouth; or after a prolonged operation in or through the mouth. Bruxism may be caused by the psychological stress of the treatment or injury. In other cases, coincidence may play a key role; where bruxism starts after trauma but is not traceable to it. Nevertheless, it may be still worth while investigating a causal connection and taking timely remedial actions, before the new bruxing habit becomes entrenched. A new “high” crown, with a high occlusal contact, may be adjusted, for example, to reduce any possible interference.

It is widely accepted in dentistry that the mandibular position and occlusal contact patterns of the teeth can influence the amount of muscle hyperactivity that takes place.¹⁴

However, although some studies have shown a positive relationship between occlusal factors and masticatory symptoms, others have shown no relationship.¹⁴ The idea that a high occlusal contact could increase muscle activity such as bruxism has been questioned. When a ligament is elongated, the nociceptive reflex is activated, causing a shutdown of the muscles that pull across the involved joint. In the mouth, the PDL is overloaded when a tooth is contacting too heavily, causing the reflex to stop the muscles that pull across the joint. With this protective mechanism in place it can not be assumed that a heavy contact could cause bruxism.

Rugh¹³ decided to challenge the concept that a premature contact could cause bruxing. He deliberately placed a crown, with a high occlusal contact, in ten subjects and observed its effects on nocturnal bruxism. Although the prevailing opinion of the dental profession was that this would lead to increased levels of bruxism, it did not. In fact, most of the subjects had a significant reduction in bruxism during the first two to four nights followed by a return to normal bruxing levels. Closer evaluation of Rugh's¹³ study revealed that a significant percentage of the subjects wearing the poorly fitting crown reported an increase in muscle pain. It is then suggested that a sudden occlusal change that disrupts the intercuspal position can lead to protective response of the elevator muscles, resulting in an increased muscle activity to protect the system and pain.

The role of occlusal interferences as an etiologic factor in bruxing has been a continuous issue for many years. As early as 1901, Karolyi postulated that occlusal interferences were an important factor in combination with psychic influences. He observed that even minor occlusal interferences could be a trigger for grinding habits in neurotic patients.⁴³

B. Stress

In some cases, emotional stress may trigger, or exacerbate, bruxism. However, the popular belief that stress is the leading *cause* of bruxism can be questioned. Negative stress has an adverse effect on health regardless of its effects on bruxism, and patients should be made aware of the destructive consequences of stress and its link to nocturnal bruxing.

Bruxism is a controversial phenomenon. Both its definition and the diagnostic procedure to identify it contribute to the fact that the literature about the etiology of this disorder is difficult to interpret. There is a consensus about the multifactorial nature of the etiology. In the past, morphological factors such as occlusal discrepancies have been considered the main causative factor, where as current focus is more on the pathophysiological factors. Further, factors like smoking, alcohol, drugs, diseases and trauma may also involved in the bruxism etiology. Psychological factors such as stress and personality are frequently mentioned in relation to bruxism as well.¹⁵

UK, Germany, and Italy combined to make up a 13,057 patients study by Ohayon, in which grinding of teeth during sleep occurring at least weekly was reported by 8.2% of the subjects. In addition, significant consequences from teeth grinding during sleep were found on half of these subjects. Moreover, 4.4% of the population fulfilled the criteria of the International Classification of Sleep Disorders (ICSD) on sleep bruxism diagnosis. Finally, subjects with obstructive sleep apnea syndrome, loud snorers, subjects with moderate daytime sleepiness, heavy alcohol drinkers, caffeine drinkers, smokers, subjects with highly stressful lifestyles. Those with anxiety were at higher risk of reporting sleep bruxism.¹⁶

A study conducted by Pierce stated that subjects with high levels of stress reported more anxiety, irritability, and depression with less denial of the stress in their life.¹⁷ Subjects who believe in a stress-bruxism relationship reported greater stress.¹⁷ Hicks completed a study just a few years prior to Pierce in which his study showed that of 511 undergraduates responding to a questionnaire, 96 identified themselves as bruxers and reported more symptoms of stress than non-bruxers. Hicks stated simply that stress may contribute etiologically to bruxism.¹⁸

A recent report by Hicks in the journal *Perception of Motor Skills* showed a four fold increase in the incidence of self reported nocturnal bruxism in college students over the last 23 years. The author stated that this emphasized the role that psychological variables may play in the development of this disorder and it is suggested that the personality traits which contribute to stress management are primary among these.¹⁹

C. Side effect of Drugs and Medications

In some cases, bruxism may be traceable to drug use. Smoking and alcohol have also been cited as contributing factors.^{20,21} Antidepressants and antipsychotic medication may also trigger bruxism in non-bruxers.²² For example, within a few days of initiating velafaxine therapy for depression, a patient with a bipolar disorder developed bruxism.²³ In another study daily intake of the antidepressant Prozac triggered sleep bruxism in four non-bruxers.²⁴ Clinicians should routinely inquire about their patient's habits of consuming tobacco, alcohol, and antidepressants.

Magnesium has a vital role in nerve and muscle function and this has led at least two researchers to the suspicion that bruxism may be traceable to insufficient

consumption of this metal. According to Ploceniak,²⁵ prolonged magnesium administration nearly always provides a cure for this type of bruxism. This confirms the report done by Lehvia in 1974 which suggests that there was a remarkable reduction in the frequency and duration of grinding episodes in six patients who took a tablet once a day of assorted vitamins and minerals for at least five weeks. When the supplements stopped, the symptoms returned.²⁶

What is the Incidence of Bruxism within the Population?

A. Adults

There are no hard and fast figures on the frequency of bruxism available. Most people unconsciously grind or clench their teeth on occasion, so the key in deciding whether someone is a bruxer is not the presence or absence of the habit, but such things as frequency, destructiveness, social discomfort, or physical symptom.²⁷

Moreover, over 80% of all bruxers may be either unaware of the habit, or ashamed of it, thereby dismissing evidence that they do engage in self-destruction behavior. Also, while it may take years for the first signs of worn teeth to appear, often it is this sign which leads to a diagnosis of past or present bruxism. For these reasons, estimates of the prevalence of bruxism range from 5 to 100%. For the US population, however current estimates have been suggested to be in the 5-20% range.²⁸

There have been multiple studies that show a marked increase in the incidence/awareness of nocturnal bruxism disease. A study conducted by Granada and Hicks²⁹ demonstrated the “incidence of nocturnal bruxism increased from 5.1% to 22.5%

over a period from 1966 to 2002.” Sleep bruxism has been reported to be 8% of the US adult population,³⁰ with no gender difference.³¹

B. Children

Nocturnal bruxism is more frequent in the younger population with a declining trend over age increase. The symptoms recognized in children can persist into adulthood. A study done in the late 1980's stated that “126 children between the ages of 6 to 9 were diagnosed with bruxism. Five years later, upon re-examination, only 17 children retained the bruxing habit. Thus, juvenile bruxism is probably a ‘self limiting condition which does not progress to adult bruxism and which appears to be unrelated to TMJ symptoms.’”³² Another study suggests that “observation and reassurance, rather than intervention, are warranted in most cases”.³³ In contrast, a more recent report by Carlsson et al, suggests that childhood bruxism might be more persistent than previously believed.³⁴

In another study by Carlsson, in which 402 children ages 7-15 were randomly selected and were examined clinically and given a questionnaire. Twenty years after the first exam, 320 completed and returned another questionnaire, and the results showed that oral parafunctions in childhood may be a persistent trait in many subjects. Subjective reports in childhood of bruxism, clenching only, grinding at night only, and nail biting and/or other parafunctional were predictors of the same oral parafunctions 20 years later.³⁴

What is the Negative Connotation of Bruxism?

I. Effect of Bruxism on Dental Restorations

This study conducted by a group of researchers in Japan evaluated 422 patients with 3673 dental restorations from 1976 to 2004, in which all the patients wore an occlusal splint during sleep. Dividing the results into three wear facet categories, the results showed that the more intense the bruxism the more likely that the dental restoration was dislodged within 15 years of placement.³⁵

Amalgam alloy restorations contain mercury. At this time, the consensus of the dental community in the USA is that the advantages of using mercury outweigh the comparatively small risks. According to the ADA “there is insufficient evidence to justify claims that mercury from dental amalgams has an adverse effect on the health of patients,”³⁶ but others claim that mercury does have adverse effects and it ought not to be used. But regardless of the outcome of this controversy, in bruxers, the situation is a bit more complicated; for there is some evidence of higher levels of mercury in the blood of bruxers with mercury fillings.³⁷ Regardless of the dental materials used, bruxism has shown destructive wear on all restorative materials including amalgam alloy, composite, gold and ceramics. A major concern for porcelain restorations is over the brittleness and tendency to fracture under destructive tones of bruxism.

II. What are some of the Evaluation Devices for Nocturnal Bruxism?

The typical, more expensive route to evaluate nocturnal bruxism is to place a patient in the sleep lab in the hospital. Here the patient is examined by the physician and then connected to an EMG. The EMG then records the muscle contractions through out the night. The cost and the time involved to perform such a test may be prohibitory for an average patient to participate. Additionally, it may be difficult for the patient to feel

“comfortable” in a hospital setting and this may lead to a different reading on the EMG versus what it would read if the patient were at home. The literature has provided us with numerous devices on the market to help with the inconvenience of a sleep lab and to aid the patient in a way that will let them record data in their own home.

Although EMG activated nocturnal alarms have been successful, the clinical utility of the devices reported in the literature to date is questionable. The Calmset is a commercially available, user-friendly, compact and portable EMG biofeedback instrument that may be used as an EMG nocturnal alarm. The results indicated with the use of this device that the patient exhibited fewer bruxing episodes following treatment and that treatment gains were maintained six months following termination of treatment.

³⁸ The objective of Dube, et al study was to compare the efficacy and safety of an occlusal splint (OS) versus a palatal control device (PCD). Patients wore each of the splints in the sleep laboratory for recording on nights three and four, two weeks apart. Both oral devices showed 50% fewer episodes with grinding noise. There were no differences was observed between the devices, and both devices reduced muscle activity.³⁹

To test the reliability of the Intra-Splint Force Detector (ISFD), multiple night recordings of forceful tooth-to-splint contacts in sleeping human subjects were recorded in their home environment. 12 subjects (6 bruxers, 6 control) over a 5 night period showed that the bruxer group exhibited bruxism events of significantly longer duration than the control group. The results suggest that the ISFD is a system that can be used easily by the subjects and that has a reasonable reliability for bruxism detection.⁴⁰

EEPROM, or Electrically Erasable Programmable Read-Only Memory, is a non – volatile storage chip used in computers and other devices to store small amounts of volatile (configuration) data. The EEPROM was installed in the device for the data recording, and after the data collection, the recorded data was entered into a personal computer via serial port. After confirming the accuracy of the device, a total of 30 subjects were enrolled in this study to monitor their bruxism activities for three nights, in which 14 of the subjects were aware of their bruxism; 16 were unaware. The bruxism self-aware group showed statistically longer average bruxism time per hour and it was confirmed that the new bruxism monitoring and analysis device is practical for clinical application to monitor and analyze nocturnal bruxism.⁴¹

A study done by Pierce evaluated the bruxcore plate on 100 nocturnal bruxers compared to the EMG reading. The results supported the conclusion that the bruxcore plate did not measure the same construct as the EMG measure, and that the bruxcore plate did effect changes in nocturnal bruxing activity.⁴²

Clinical indication of sleep bruxism is usually based on examination of the teeth, complaints of jaw and masticatory pain, and subjective reports of the grinding and/or clenching noise (usually provided by the bed partner or family member).

Currently the only “gold standard” for a definitive, objective diagnosis of sleep bruxism is the measurement of jaw muscle activity using a muscle activity recorder (EMG). Clinical diagnosis in the sleep laboratory with polysomnographic (PSG) recordings is rare due to the high costs of this type of study.

The introduction of the BiteStrip^R makes true EMG based diagnosis possible at a reasonable cost. The device, which monitors jaw muscle EMG signals throughout the night, performs automatic analysis based on the criteria described above, to produce a clinically validated indication of the presence of bruxism in the morning.

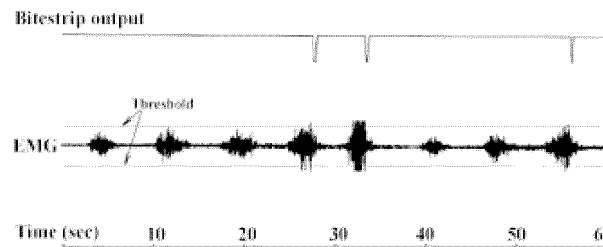


Figure 1

III. Proposed Treatment for Nocturnal Bruxism

Bruxism is of extreme clinical importance in treatment planning. It is essential for the successful treatment of any disorder of a dysfunctional nature like bruxism that the etiologic factors be recognized and that the causative factors are eliminated. The complexity of the etiology of bruxism and the diagnostic problems to identify it make it easy to understand the current state of confusion and controversy that exists about the treatment of bruxism.

For clinical success of treatment, bruxism should be reduced below the level at which it is capable of producing recognizable harm to the teeth, the periodontium or any other part of the masticatory system. Currently it is still questioned whether the elimination of the occlusal trigger areas is the treatment of first choice, and if bruxism may be eliminated or controlled by precise occlusal adjustments.

The following are some treatments that need to be considered when you have a patient that shows signs and symptoms of bruxism.

Stress management: Professional counselling or strategies that promote relaxation, such as exercise and meditation may be helpful. Keeping life stresses to a minimum may reduce the risk of developing bruxism. With a patient, the less anxiety and tension, the better chance of avoiding bruxism.

Dental approaches: A mouth guard or protective dental appliance (splint) can prevent damage to the teeth and gums. If bruxism seems to stem from dental problems, the dentist may also correct misaligned teeth. In severe cases, when tooth wear has led to sensitivity or the inability to chew properly, the dentist may need to use overlays or crowns to entirely reshape the chewing surfaces of your teeth.

Behaviour therapy: Behavioural change by practicing proper mouth and jaw position may be appropriate. The recommendations call for resting the tongue upward with the teeth apart and lips closed. This should keep the teeth from grinding and the jaw from clenching. It may be beneficial to use biofeedback, a form of complementary and alternative medicine that uses a variety of monitoring procedures and equipment to teach the patient to control involuntary body responses.

Limit alcohol, tobacco and caffeine. Cutting down on daily intake of alcohol, tobacco and caffeine, or giving up these substances entirely, may help, because they seem to make bruxism worse.

Medications: In general, medications aren't very effective for treatment of bruxism. In some cases, a doctor may suggest taking a muscle relaxant before bedtime. If bruxism developed as a side effect of an antidepressant medication, the doctor may change the

medication or prescribe another medication to counteract bruxism. Botulinum toxin (Botox) injections may help some people with severe bruxism that hasn't responded to other treatments.

Consult the sleep partner. Consulting the roommate or bed partner, to be aware of any grinding or clicking sounds while sleeping. The sleep partner can then provide continuous feedback on any teeth-grinding sounds in the night.

Have regular dental exams. Dental exams, preferably with the BiteStrip prescribed by a dentist, are the best way to screen against bruxism.

What are the current criteria for diagnosing nocturnal bruxism?

Based on the American Sleep Disorder Association (ASDA) there are certain diagnostic criteria for nocturnal bruxism. The following is a list of the criteria and according to ASDA at minimum the first two criteria must be present for a diagnosis.

1. The patient has a complaint of tooth grinding or tooth clenching during sleep
2. One or more of the following is present:
 - Abnormal wear of the teeth
 - Sounds associated with bruxism
 - Jaw muscle discomfort
3. Polysomnographic monitoring demonstrates both:
 - Jaw muscle activity during the sleep period

- Absence of associated epileptic activity

4. No other medical, mental or sleep disorders

There is also a classification of nocturnal bruxism from the ASDA based on the severity of the bruxing.

Mild: Episodes occur less than nightly, without evidence of dental injury or impairment psychosocial functioning.

Moderate: Episodes occur nightly, with evidence of mild impairment of psychosocial functioning.

Severe: Episodes occur nightly, with evidence of dental injury, TMD, other physical injury, or moderate or severe impairment of psychosocial functioning.

How is the dental field currently responding to patients with Nocturnal Bruxism?

The evidence of damage to teeth is so routinely ignored, both in clinical practice and in the dental curricula. It is still more bewildering if one recognizes that signs of occlusal disease are so easily observed even at the earliest stages when progression of the damage can usually be intercepted. Symptoms of occlusal disease may not be as obvious, but when both signs and symptoms are readily recognized the patient typically responds to treatment at a high level of predictability.⁴³

Attention to occlusion would be elevate to a much higher priority if the following observations were more universally noticed and analyzed.

Occlusal disease is:

- The most common destructive dental disorder.
- A contributing factor to eventual loss of teeth.
- A reason for needing extensive restorative dentistry.
- A factor associated with discomfort within masticatory system structure. This includes pain/discomfort in the musculature, the teeth, and the region of the TMJs.
- A factor in instability of orthodontic treatment.
- A reason for tooth soreness and hypersensitivity.
- A most commonly missed diagnosis leading to unnecessary endodontics.
- A most undiagnosed dental disorder until severe damage became too obvious to ignore.

The above observations have not, at this date, been confirmed by formal evidence based protocols, but they are consistent with many years of careful observation of thousands of Dr. Peter Dawson's patients.⁴³ Attention to periodontal disease and control of caries have become more consistent to most dental practices, but a complete evaluation of occlusal disease is incomplete in too many examinations.

Lytle⁴⁴ was the first to introduce the term occlusal disease. At that time he defined it as "the process resulting in the noticeable loss or destruction of the occluding surfaces of the teeth." He postulated that the disease is primarily but not necessarily precipitated by bruxism or parafunction.

Dawson states that "when signs and symptoms of bruxism are observed, a meticulous occlusal examination is in order. Regardless of whether the cause is

emotional stress or occlusal triggers, the occlusion should be perfected. Whether treatment for bruxism is directed at eliminating the cause or the effects of the problem is at this point academic. It appears that regardless of the cause, the most effective treatment of the effects of bruxism is perfection of the occlusion.”⁴⁴

CHAPTER 3

MATERIALS AND METHODS

Twenty subjects, 10 female and 10 male, ranging in age from 15 to 74 with a mean age of 34 years, were selected from the West Virginia University School of Dentistry Graduate Prosthodontics population for inclusion in the study. The subjects acted as test subjects and served as their own controls. All subjects were screened by conducting an oral exam and a written questionnaire (Appendix A). The main criteria for selection were (1) at least 18 years old or had written consent by parent/guardian if not 18, (2) be in good general health, (3) no history of medications, drug use or treatments that could affect mandibular movements, (4) present with an intact dentition with at least twenty four net teeth, (5) be informed of the description of the instrument and procedures to be performed (form attached), and (6) sign consent form. (Appendix C)

After a written and oral investigation of the subjects' dental health, the investigator decided to accept the patient into the study if one or more of the signs and symptoms of bruxism were present. The signs and symptoms of bruxism may include: (1) teeth grinding or clenching, which may be loud enough to wake the sleep partner, (2) teeth that are worn down, flattened, or chipped, (3) worn tooth enamel, exposing the inside dentin, (4) increased tooth sensitivity, (5) jaw pain or tightness in jaw muscles, (6) earache because of violent jaw muscle contractions, (7) dull morning headache, (8) chronic facial pain, and/or (9) chewed tissue on the inside of the cheeks.

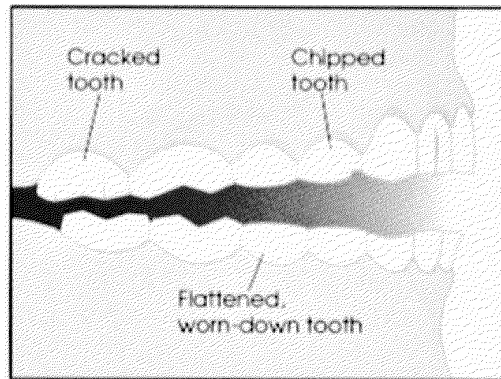


Figure 2

The BiteStrip^R is proposed to identify the existence and frequency of bruxism. This single use home screening device can be used to evaluate the need for bruxing therapy, treatment of a malocclusion, occlusal restoration, snoring and sleep apnea treatment, and TMJ therapies and surgical outcomes according to the manufacture.

When determining an appropriate technique or the most effective material to use when planning a restorative procedure or occlusal treatment, the presence and frequency of bruxism must be considered. A patient who bruxes can destroy a costly appliance or restoration and significantly delay treatment. Screening results also serve as a basis to educate the patient about the existence of bruxing.

Once the patient was selected, a written questionnaire was given to the subject. The patient was then given a demonstration of how the BiteStrip^R was to be placed on the cheek and how it works. The patient received a written demonstration form as well. (Appendix B) The patients were told that they must receive at least six hours of rest for the device to work properly. They were also told to return their BiteStrip^R within one week for documentation. The data was recorded and a Wilcoxon ranked sums test with a two sample and a one sample test were used to compare the results.

Description:

The BiteStrip^R is a single-use disposable device designed as a front line screener for nocturnal bruxism. It is a miniature electronic system comprising of:

- Two pre-gelled skin EMG electrodes and an EMG amplifier, for acquiring nocturnal EMG signals from the masticatory muscles.
- A CPU for running real-time software that analyzes EMG strength patterns and for detecting and counting each bruxing episode.
- A permanent chemical display for presenting the study outcome in the morning.
- A lithium battery
- All the elements are integrated onto a single flexible substrate.

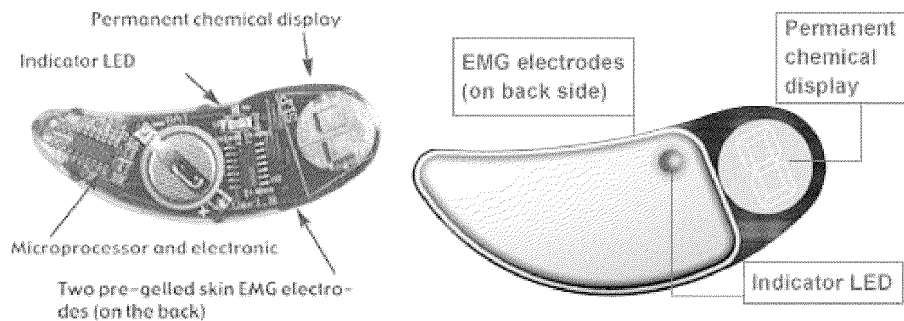


Figure 3

The green sticker carries a layer of hydrogel material which serves two purposes: (1) At the beginning of the study the gel closes an electrical circuit to activate the device (like an on/off button). (2) At the end of the study, the gel is used as a chemical component in etching the result on the display. The patient was specifically instructed to

wait 45 minutes before removing the green sticker from the display after the study ends, as this is the time it takes to etch the result onto the display.

The result is permanent. It is etched on to the display 30 minutes after the study ends. Due to the possibility of corrosion, however, it was recommended not to wait more than three months before returning the BiteStrip^R to the dentist. After the green sticker is removed, the display is readable for at least five years.

Patient Instructions:

Step 1: remove contents of the BiteStrip^R package; the BiteStrip^R, green sticker, and alcohol pad.

Step 2: Wash your face with soap and water and dry well.

Step 3: Remove BiteStrip^R and green sticker from the wrapper. Using the alcohol pad, rub the display area once or twice to prepare the surface for placement of the green sticker.

Step 4: Peel the green sticker from its white paper cover and attach it firmly to the display area. The red light will begin blinking and remain blinking until it is placed over the masseter muscle.

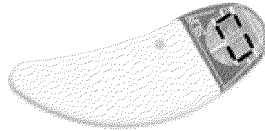


Figure 4

Step 5: Place your left hand on your left cheek just above your jaw line. Clench your teeth to locate the masseter muscle. This is the proper site to place the BiteStrip^R.

Step 6: Peel the protective cover from the back of the BiteStrip^R and apply it firmly to the masseter muscle identified in the previous step. The red light will stop blinking in a few seconds.

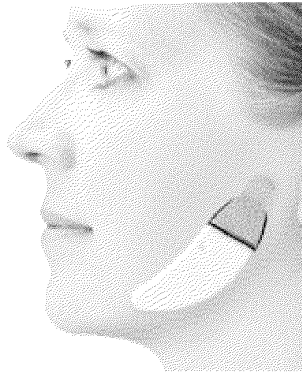


Figure 5

Soon after placing the BiteStrip^R, you must activate it.

Step 7: Using a mirror, clench your teeth as hard as you can for 2 seconds, then relax. Repeat 3 more times. The red light will blink during each clench. The two strongest clenches detected by the BiteStrip^R during the activation process will be used to establish the baseline.

Step 8: The BiteStrip^R is now activated. You should go to sleep as soon as possible. Do not remove the BiteStrip^R for a period of at least six hours.

Step 9: after sleeping for at least six hours, gently remove the BiteStrip^R from your face.

Step 10: Do not remove the green sticker from the BiteStrip^R. The data is now collected. Return the BiteStrip^R to your doctor to interpret the study results. Use the enclosed envelope or return it in person as directed by your doctor.

Understanding the Operation:

The patients were instructed to perform at least two maximal voluntary clenches (MVCs) during the first 20 minutes is because the two strongest EMG peaks detected during this period are used to establish the threshold, which was set at 30% of their average amplitude. It was therefore very important to make sure the patient performed this maneuver shortly after applying the device on the face in order to avoid picking up every small twitch during the night.

The BiteStrip^R counts each EMG peak stronger than the threshold for a period of up to six hours. Removing the BiteStrip^R in under four hours results in an error as four hours is considered the minimum period for a significant indication.

The counting stops after six hours, but the device may remain in place for up to 12 hours. A study longer than 12 hours is also considered to be in error because it may indicate a technical problem in the device.

The study ends once the BiteStrip^R is removed from the face. The red light turns on within two minutes after removal. The display is ready for reading 30 minutes later. The green sticker should not be removed before this time or the display will be difficult to read.

The display presents a number that indicates the severity of bruxism during the study.

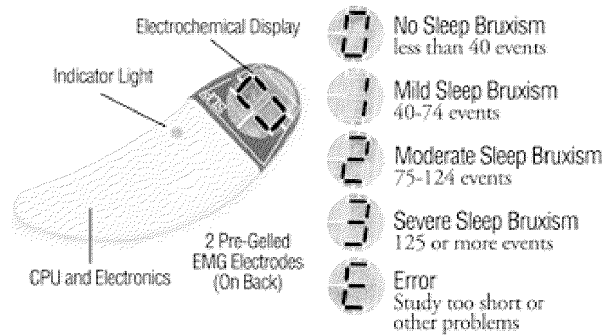


Figure 6

Any reading other than 0 is considered positive for nocturnal bruxism. Clinical studies demonstrated good sensitivity (over 80%) for mild cases of nocturnal bruxism very good sensitivity for moderate cases of nocturnal bruxism and excellent sensitivity for severe cases.

CHAPTER 4

RESULTS AND DISCUSSION

Results:

Nocturnal bruxism is believed to be a stress-related sleep disorder. This study evaluated 20 patients from the West Virginia University Graduate Prosthodontic program on what the patients thought they knew about their own personal nocturnal bruxism compared to what the BiteStrip^R revealed whether, nor not they actually do brux, and if so to what degree. Six of the patients (30%) had previously been informed by a dentist/hygienist that they had signs of occlusal wear, and 9 (45 %) of the patients stated that they were aware of their own clenching at night. Of those 9 patients that were aware of the clenching, 4 (44%) stated that their bed partners had complained about it; 2 (22%) stated that they have woken up with pain or stiffness in their jaws; only 1 out of the 9 said they had a headache in the morning; no one had any difficulty in opening their mouth in the morning; and 2 out of the 9 said that they noticed clicking in their jaw joints.

A total of 14 of 20 patients actually demonstrated nocturnal bruxism with the BiteStrip^R. 6 of the 20 did not demonstrate having any significant signs of bruxism and 5 of those 6 stated they did not brux according to the responses on their questionnaire (Appendix A, questions #1).

9 patients said that they did brux and their scores ranged from 1 to 3, with over 50% of them with a score of 3. Only one person said that they brux at night and actually had a score of 0.

The following table shows each patients age, sex, score, and answer to each question in appendix A.

Table 1:

#	AGE	SEX	SCORE	1	2	3	4	5	6	7
1	61	F	3	YES	NO	YES	NO	NO	NO	NO
2	25	F	0	NO	NO	NO	NO	NO	NO	NO
3	27	M	2	YES	YES	NO	NO	NO	NO	NO
4	74	M	0	NO	NO	NO	NO	NO	NO	YES
5	29	F	3	YES	NO	YES	NO	NO	NO	NO
6	53	M	2	YES	YES	NO	NO	NO	NO	YES
7	64	M	2	YES	NO	NO	NO	NO	NO	YES
8	41	F	0	YES	NO	NO	YES	NO	YES	YES
9	49	F	1	NO	NO	NO	NO	NO	NO	NO
10	31	M	1	YES	NO	NO	NO	NO	NO	NO
11	29	F	0	NO	NO	NO	NO	NO	NO	NO
12	32	M	1	NO	NO	NO	NO	NO	NO	NO
13	25	M	0	NO	NO	NO	NO	NO	NO	NO
14	28	M	1	NO	NO	NO	NO	NO	NO	NO
15	31	M	2	NO	NO	NO	NO	NO	NO	NO
16	28	F	0	NO	NO	NO	NO	NO	NO	NO
17	15	F	2	NO	NO	NO	NO	NO	YES	NO
18	39	F	1	NO	YES	YES	YES	NO	NO	NO
19	61	F	3	YES	YES	NO	NO	NO	YES	YES
20	38	M	3	YES	YES	NO	NO	NO	NO	YES

The above table was statistically analyzed with Wilcoxon/Kruskal-Wallis test of ranked sums. It is to test the null hypothesis that there is no difference in the two population distributions. With this test we assume that we have a series of pairs of dependent observations. We wish to test the hypothesis that the median of the first sample equals the median of the second; that is, there is no differences between the

outcomes before and after some condition to favor the before or the after condition. Of all 7 questions, only question # 1 and # 2 came out statistically significant when compared to the score of the BiteStrip^R.

1: In the 2-Sample Test ($p = 0.0085$) and in the 1-sample test ($p = 0.0076$).

2 : In the 2-Sample Test ($p = 0.0581$) and in the 1-sample test ($p = 0.0524$).

Table 2:

Wilcoxon / Kruskal-Wallis Test (ranked sums)

Level	Count	Score Sum	Score Mean	Stand. Dev.
no	11	81.5	7.4091	-2.637
yes	9	128.5	14.2778	2.631

2- Sample Test, Normal Approximation

S	Z	Prob> Z
128.5	2.63057	0.0085

1- Sample Test, ChiSquare Approximation

ChiSqare	DF	Prob>ChiSq
7.128	1	0.0076

Table 3:

Wilcoxon / Kruskal-Wallis Test (ranked sums)

Level	Count	Score Sum	Score Mean	Stand. Dev.
no	15	136	9.0667	-1.895
yes	5	74	14.8	1.895

2- Sample Test, Normal Approximation

S	Z	Prob> Z
74	1.89457	0.0587

1- Sample Test, ChiSquare Approximation

ChiSquare	DF	Prob>ChiSq
3.7624	1	0.0524

If $p < 0.05$ it is statistically significant and thus leads us to reject the null, that there is no difference between the two. That is that there is a difference between the score and the patients' answer of awareness.

Discussion:

From this small clinical study of 20 patients the BiteStrip^R identified the existence and frequency of bruxism. This new device is claimed by the manufacture to be a single use home screening device to confidently and precisely prepare for and evaluate bruxing

therapy, treatment of a malocclusion, occlusal restoration, snoring and sleep apnea treatment, and TMJ therapies and surgical outcomes.

Our results showed that 70% of our patient population demonstrated nocturnal bruxism. This figure is much higher than the report by Thompson, Blount, and Krumhotz in 1994.²⁸ They stated that for the United States population the current estimates have been suggested to be in the 5 – 20% range.

Our outcome of 70% is high but according to a study conducted by Granada and Hicks²⁹ which showed that bruxism is on a rise. They stated that over a 35 year period bruxism has increased from 5.5% to 22.5%. A study done recently by Unell⁵¹ stated that from 1992 to 2002 reported bruxism rose from 18% to 28 %. With this study's population was expected to have a high percentage of bruxers because participants were selected who had at least one symptom of nocturnal bruxism.

When Winocur et al,⁴⁵ did their study in 2006, they showed that when they compared 50 healthy patients to 77 psychiatric stressed patients, bruxism was more evident in the stressed patient with 46.8% of the population versus 20% in normal patients. In an Air Force study on pilots versus non pilots, they found that only 27% of the non-pilots bruxed while 67% of the pilots' bruxed.⁴⁶ Yet, there was not a difference in the stress levels of the pilots versus non-pilots.

In a study done by Cooper,⁴⁷ he followed his patients by examining them for 25 years. Out of 4, 528 patients all but 110 showed some signs/symptoms up exam. When given a questionnaire, 79.3% stated that they had dull headaches in the morning; 96.1%

they have some type of jaw pain/discomfort during the day or when they awake in the morning. Of the 4,338 patients who showed signs/symptoms upon exam, 85.1 % had muscle tenderness upon palpation. This is much higher than what was found in this study, which showed that 11% had dull headaches in the morning and 20% had pain or stiffness in the jaws when they woke up in the morning.

In a study done in 2003 by Pergamalian⁴⁸ which took 84 patients that stated that they had been told by previous dentist/doctors that they show signs of wear. Of the 84 patients, 11.4 % reported no bruxing, 32.1% reports some bruxing, and 47.6% had severe bruxing, with the remainder 8.4% being eliminated because of inconsistent responses. According to this study the 20 patients using the bite strip, 6 had been told previously that they show signs of wear. Of the 6, 33 % showed no bruxing (score of 0), 66% showed severe signs (score of 2 or 3). No one of the six showed slight/some bruxing (score of 1).

When we compared gender in this study, 6 out of 10 female's bruxed, while 8 out of 10 males bruxed. In comparison to a study done by Mundt et al⁴⁹, they found that when they compared bruxing in women versus men, it was 2:1.

Prior to testing, 11 of the patients stated they did not brux. With the BiteStrip^R 6 of these 11 demonstrated nocturnal bruxing. Over 50 % of the participants in this study indicated they did not have nocturnal bruxism, of these, 6 patients did actually brux. When we compare our study to a study done by Manfredini in 2005⁵⁰, he stated that when 98 of his subjects were given a self report questionnaire, 34.7% of them were actually diagnosed as bruxers, which is a lower percentage than what we found.

When determining an appropriate technique or the most effective material to use when planning a restorative procedure or occlusal treatment, the presence and frequency of bruxism must be considered. A patient who bruxes can destroy a costly appliance or restoration and significantly delay treatment. Screening results also serve as a basis to educate the patient about the existence of bruxing.

CHAPTER 5

SUMMARY AND CONCLUSION

Summary:

11 out of 20 stated that they were not aware of their bruxism. Of the 11 patients, 6 (55%) actually did show a score of 1 or greater, meaning that they were unaware of their nocturnal bruxism. Only one person out of the 11 that said no to the awareness stated that their spouse was complaining of their bruxing, and that same person also stated that they had dull headache usually in the morning.

Conclusions:

In a patient population of suspected bruxers, the BiteStrip^R demonstrated that 70% of these patients registered as bruxers. A fairly high percentage of those who scored as bruxers with the BiteStrip^R were unaware that they did brux. Considering the highly destructive nature of bruxism, the BiteStrip^R appears to be a good method of designating these patients so that treatment intervention can be instituted.

Since a large percentage of patients are unaware of their bruxism habit and since the clinical signs of bruxism are inconclusive, the BiteStrip^R may be very helpful to the

dentist in determining whether the patient will be placing the destructive forces on the
teeth and restorations.

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APPENDIX A

Patient Questionnaire

Are you clenching and grinding your teeth at night?
You may be a bruxer and don't know it.

**Answer the following questions to determine if
bruxism is causing damage to your teeth.**

- | | | |
|--|------------------------------|-----------------------------|
| Do you clench your teeth tightly while sleeping? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Does your bed partner complain that you grind your teeth while sleeping? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you feel pain, stiffness, or weariness in your jaw joint when you wake up? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you wake up with a dull morning headache? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you have difficulty opening your mouth when you wake up? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you hear a "clicking" sound when you open your mouth the first time in the morning? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Did you notice or have you even been told that your teeth are showing signs of wear? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

APPENDIX B

How to Use the BiteStrip™

IMPORTANT: Please read all the instructions prior to beginning the study. Carefully following the instructions is essential to obtaining accurate study results. Preparation of the BiteStrip should be the last thing you do before going to sleep (for at least 6 hours).

Preparing the BiteStrip

For optimal results, a well-lit room and a large mirror are recommended.

Step 1: Remove contents of the BiteStrip package: the BiteStrip, green sticker, and alcohol prep pad.

Step 2: Wash your face with soap and water and dry well.

Step 3: Remove BiteStrip and green sticker from the wrapper. Using an alcohol pad, rub the display area once or twice to prepare the surface for placement of the green sticker.

Step 4: Peel the green sticker from its white paper cover and attach it firmly to the display area. The red light will begin blinking and remain blinking until it is placed over the masseter muscle.

Placing the BiteStrip

Step 5: Place your left hand on your left cheek just above your jaw line. Clench your teeth to locate the masseter muscle. This is the proper site to place the BiteStrip.

Step 6: Peel the protective cover from the back of the BiteStrip and apply it firmly to the masseter muscle identified in the previous step. The red light will stop blinking in a few seconds.

Soon after placing the BiteStrip, you must activate it.

Activating the BiteStrip

Step 7: Using a mirror, clench your teeth as hard as you can for 2 seconds, then relax. Repeat 3 more times. The red light will blink during each clench. The two strongest clenches detected by the BiteStrip during the activation process will be used to establish the baseline.

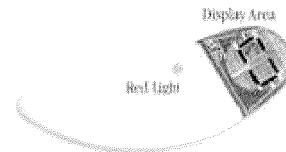
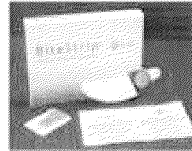
Step 8: The BiteStrip is now activated. You should go to sleep as soon as possible. Do not remove the BiteStrip for a period of at least six hours.

Removing the BiteStrip

After sleeping for at least six hours, gently remove the BiteStrip from your face.

DO NOT remove the green sticker from the BiteStrip. The data is collected and analyzed for more than an hour after the BiteStrip is removed.

Return the BiteStrip to your doctor to interpret the study results. Use the enclosed envelope or return it in person as directed by your doctor.



APPENDIX C

CONSENT AND INFORMATION FORM

The Efficacy of the BiteStrip in Determining Patients Awareness of Nocturnal Bruxism

Introduction

You, _____, have been asked to participate in this research study, which has been explained to you by Becky Tolley D.D.S.; Mark Richards D.D.S, Med; Mohssen Ghalichebaf D.D.S. This study is being conducted by Dr. Tolley, Dr. Richards, Dr. Ghalichebaf in the Department of Restorative Dentistry at West Virginia University with funding provided by UHA Dental Corporation.

This research is being conducted to fulfill the requirements for a Master of Science with a Certificate in Prosthodontics in the Department of Restorative Dentistry at West Virginia University, under the supervision of Dr. Richards and Dr. Ghalichebaf.

Purposes of the Study

The purpose of this study is to compare the incidence of nocturnal bruxism determined by an electronic device when compared to self-reporting from verbal or written dental histories.

WVU expects to enroll a total of approximately 20 subjects.

Description of Procedures

This study involves you (the patient) filling out a questionnaire about your awareness of nocturnal bruxism. Then you will be evaluated by Dr. Tolley for any signs or symptoms of bruxism. After your initial exam you will be instructed on how to use the BiteStrip. You will then wear the device while you get a full nights sleep. You will then return the BiteStrip back to Dr. Tolley who will tell you your results. It will take approximately two hours for you to complete the entire process and will be completed in two appointments and one nights sleep. You will be screened for jaw muscle and joint problems using the questionnaire called "The Bruxism Survey". This will take you approximately 10 minutes.

Risks and Discomforts

There are no known or expected risks from participating in this study, except for the mild discomfort associated with moving your lower jaw.

Submission date _____

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Alternatives

You do not have to participate in this study.

Benefits

You may not receive any direct benefit from this study.

Financial Considerations

No payments will be made for participating in the study.

Confidentiality

Any information about you that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by federal regulatory authorities without your additional consent.

In addition, there are certain instances where the researcher is legally required to give information to the appropriate authorities. These would include mandatory reporting of infectious diseases, mandatory reporting of information about behavior that is imminently dangerous to you or to others, such as suicide, child abuse, etc.

In any publications that result from this research, neither your name nor any information from which you might be identified will be published without your consent.

Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time.

Refusal to participate or withdrawal will not affect your future care, or your class standing or grades, and will involve no penalty to you.

In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation.

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The Efficacy of the BiteStrip in Determining Patients Awareness of Nocturnal Bruxism

You have been given the opportunity to ask questions about the research, and you have received answers concerning areas you did not understand.

Upon signing this form, you will receive a copy

I willingly consent to participate in this research.

Signature of Subject or Subject's Legal Representative

Printed Name

Date _____ Time _____

The participant has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

Signature of Investigator or Co-Investigator

Printed Name

Date _____ Time _____

Contact Persons

In the event you experience any side effects or injury related to this research, you should contact Dr. Tolley at (304) 293-6208. For more information about this research and about research-related risks or injury, you can contact Dr. Tolley or Dr. Richards at (304) 293-7101. For information regarding your rights as a research subject, you may contact the Office of Research Compliance at 304/293-7073.

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CURRICULUM VITAE

Biographical Data:

Name:	Emily Rebecca Tolley
Date of Birth:	January 19, 1978
Place of Birth:	Clarksburg, WV

Education:

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West Virginia University	D.D.S.	2004
West Virginian Universtiy	M.S., Certificate in Prosthodontics	2007